Via Surgical

Pre Market Notification Submission – 510(k)

510(K) SUMMARY
FasTouch Fixation System
510(k) Number K132698

5.1 Company Name

Via Surgical Ltd.
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5.2 Contact Person

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NorthStar Biomedical Associates for
Via Surgical Ltd.
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And/or

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5.3 Trade/Proprietary Name

FasTouch Fixation System

5.4 Classification Name

Staple Implantable

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5.5 Product Code/Regulation No.
Implantable staple, product code: GDW, Regulation No. 878.4750.

5.6 Device Classification
Class II

5.7 Panel
General & Plastic Surgery

5.8 Predicate Devices
1. Ethicon LLC SECURFSTRAP 5mm Absorbable Strap Fixation Device, cleared under K093845, (product code GDW, Regulation No. 878.475).
2. Davol Inc. Bard PermaFix Fixation System, K092483 (product code GDW, Regulation No. 878.475).

5.9 Intended Use
The FasTouch Fixation System is intended for fixation of prosthetic material to soft tissues in various minimally invasive and open surgical procedures such as hernia repairs.

5.10 Device Description
The FasTouch Fixation System is a manual laparoscopic surgical instrument which is intended to facilitate fixation of prosthetic material to soft tissue in laparoscopic or open surgical procedures such as ventral hernia repair. The FasTouch Fixation System is disposable, single-use system.

The Via Surgical's FasTouch Fixation System is designed to be inserted through a laparoscopic port sleeve but may be used during open surgical procedures as well. The FasTouch Fixation System is packaged in its unloaded state and contains a handle and a cartridge.

The FasTouch Handle is a multi-fire, sterile, single-use handle that is compatible to work with Via Surgical's FasTouch cartridges (25PS cartridge).

5.11 Performance Standards
No performance standards have been established for such device under Section 514 of the Federal Food, Drug, and Cosmetic Act.

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5.12 Substantial Equivalence

Via Surgical Ltd. believes that the FasTouch Fixation System is substantially equivalent to the legally marketed predicate devices due to the following reasons:

A) The same intended use and indications for use as the predicate devices.
B) All devices use a similar fixation technology to deliver the fasteners by compressing a trigger.
C) Similar fastener strap design to the fasteners used with the SecureStrap predicate and similar non-absorbable polymer material as used in the PermaFix predicate.
D) Similar technological characteristics to the predicate devices such as: trigger handle, penetration depth, spring load firing mechanism and shaft length.
E) Same principle of operation.
F) Similar materials.

As demonstrated in the completed battery of preclinical tests that were conducted by the company minor technological differences between the FasTouch Fixation System and the predicate devices do not raise new questions of safety and effectiveness. Any minor differences in technological characteristics have been tested and reported on in this notification and demonstrate that any differences do not adversely affect the safety, effectiveness, or intended performance of the device. Therefore, the FasTouch Fixation System is substantially equivalent to the legally marketed predicate devices. Testing included laboratory bench testing, biocompatibility testing, animal testing, and clinical usability testing.

5.13 Performance Characteristics of the FasTouch Fixation System

The FasTouch Fixation System underwent a full battery of bench testing, animal testing, and biocompatibility testing to demonstrate its safe and effective performance in fixation of prosthetic material (e.g., hernia mesh) to soft tissues. In addition, clinical usability testing was conducted. It was concluded that the device is safe and effective for its intended use. Tests were performed with variety of market-cleared mesh types and sizes using the FasTouch Fixation System. In addition, tests were done in comparison to the predicate devices. Specifically, testing included:

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- Device Cartridge loading and replacement (BT-011)
- Fixation strength evaluation (BT-012)
- Mesh compatibility and Integrity following fixation with the FasTouch Device (BT-013)
- Performance Evaluation (BT-014)
- Animal study for deployment and fixation including surgeons feedback
- Clinical usability test

All testing performed demonstrated that the FasTouch Fixation System is a safe and effective device for facilitating the fixation of soft tissue prosthetics during the laparoscopic repair of hernia and is considered substantially equivalent to its predicate devices.

5.14 Conclusion

Via Surgical Ltd. believes that, based on the descriptive and test information provided in this submission, the FasTouch Fixation System is substantially equivalent to its predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

Via Surgical Ltd.
% Mr. Leo Basta
Northstar Biomedical Associates
93 Benefit Street
Providence, Rhode Island 02904

March 14, 2014

Re: K132698
Trade/Device Name: Fastouch Fixation system
Regulation Number: 21 CFR 878.4750
Regulation Name: Implantable staple
Regulatory Class: Class II
Product Code: GDW
Dated: February 10, 2014
Received: February 11, 2014

Dear Mr. Basta:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you: however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

David Krause -S

for Binita S. Ashar, M.D., M.B.A., F.A.C.S.
Acting Director
Division of Surgical Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATIONS FOR USE STATEMENT

510(k) Number (if known): K132698

Device Name: FasTouch Fixation System

Indications for Use:

The FasTouch Fixation System is intended for fixation of prosthetic material to soft tissues in various minimally invasive and open surgical procedures such as hernia repairs.

Prescription Use ✓ AND/OR Over-The-Counter Use___
(Part 21 C.F.R. 801 Subpart D) (21 C.F.R. 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE -- CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Peter L. Hudson -S
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